DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

HFI-35

M874N

MAY 1 1997

WARNING LETTER

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

Mr. Peter Killcommons, M.D., President
Medweb, Inc.
667 Folsom Street
San Francisco, California 94107

Dear Mr. Killcommons:

The Food and Drug Administration's (FDA) Center for Devices and Radiological Health has received information (copy enclosed) that Medweb, Inc. has been advertising and commercially introducing the Medweb Radiology Workstation Plugin for Netscape Navigator. This teleradiology system is a device as defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Your teleradiology system is adulterated within the meaning of section 501(f)(1)(B) of the Act, in that it is a Class III device under section 513(f) and does not have an approved application for premarket approval in effect pursuant to section 515(a) or an approved application for an investigational device exemption under section 520(g).

Your teleradiology system is misbranded within the meaning of section 502(o) of the Act, in that the device was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under section 510, was not included in a list required by section 510(j), and a notice or other information respecting the modifications to the device was not provided to the FDA as required by section 510(k) and Title 21, Code of Federal Regulations (CFR), Section 807.81(a)(3)(ii).

Please be advised that your teleradiology system provides features (e.g., Web connectivity, Netscape interface, and wavelet compression) which were not covered in premarket notification number K950413, which you claimed covered the system during your telecon of March 13, 1997, with Ms. Xuan T. Vo of my staff.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to the attention of Ms. Xuan T. Vo of the Diagnostic Devices Branch, Division of Enforcement I at the above letterhead address, with a copy to the San Francisco District Office, Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, California 94502-7070.

Sincerely yours,

for/ Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health

Enclosure